SUMMARY ELIGIBILITY CRITERIA

optima
personalised treatment of breast cancer

INCLUSION CRITERIA

- Female or male, age ≥ 40.
- Excised invasive breast cancer with local treatment either completed or planned according to trial guidelines.
- ER positive (with >10% cells staining +ve*) AND HER2 negative.
  **Allred score 6-8 tumours are eligible; for scores 4-5, %staining component is required to determine eligibility. Refer to the protocol for full guidance.*
- Tumour size and axillary lymph node status; one of the following must apply:
  i. 4-9 lymph nodes involved AND any invasive tumour size.
  ii. 1-3 nodes involved, with at least 1 node containing a macrometastasis (i.e. deposit >2mm diameter) AND any invasive tumour size.
  iii. 1-3 lymph nodes involved with micrometastases only (i.e. deposit >0.2-2mm diameter) AND invasive tumour size ≥ 20mm.
  iv. node negative AND invasive tumour size ≥ 30mm.
- Considered appropriate for adjuvant chemotherapy by treating physician.
- Patient must be fit to receive chemotherapy and other trial-specified treatments with no concomitant medical, psychiatric or social problems that might interfere with informed consent, treatment compliance or follow up.
- Multiple ipsilateral cancers are permitted provided at least one fulfils the size & lymph node entry criteria and none meets any of the exclusion criteria.
- Bilateral cancers are permitted provided the tumour(s) in one breast meets the eligibility criteria and the contralateral tumour is not ER negative and/or HER2 positive AND is not clinically significant*.
  **Refer to full eligibility criteria for definition of clinical significance.*
- Short term pre-surgical treatment with endocrine therapy including in combination with non-cytotoxic agents is allowed providing that the duration of treatment does not exceed 8 weeks.
  A pre-treatment core biopsy should be sent to the Central Laboratory if pre-surgical endocrine therapy has been given.
- Informed consent for the study.

EXCLUSION CRITERIA

- ≥10 involved axillary nodes (macrometastases and/ or micrometastases) or involvement of any of internal mammary, supraclavicular and infraclavicular lymph nodes.
- ER negative/low positive (≤10% ER staining) OR HER2 positive/amplified.
- Metastatic disease.
- Previous diagnosis of malignancy unless:
  i. managed by local treatment only AND disease-free for 10 years.
  ii. ductal carcinoma in situ (DCIS) or pleomorphic lobular carcinoma in situ (pleomorphic LCIS) of the breast managed by local treatment only; treatment with anti-oestrogens is not permitted.
  iii. NOTE: Isolated classical type lobular carcinoma in situ (LCIS) is not considered in this context to be a diagnosis of malignancy.
  iv. any other in situ carcinoma as defined by the International Classification of Diseases for Oncology (ICD-O) including basal cell carcinoma of skin and cervical intraepithelial neoplasia.
- Pre-operative anti-cancer treatments except short-term pre-surgical endocrine therapy as per the inclusion criteria.
- Adjuvant systemic treatment commenced prior to trial entry except endocrine therapy, which must be discontinued prior to starting trial allocated chemotherapy.
- Treatment with agents, including ovarian suppression, known to influence breast cancer growth but prescribed for other indications within one year of trial entry except as follows:
  i. Use of oestrogen replacement therapy (HRT) provided this is stopped before surgery.
  ii. Drugs administered for in vitro fertilization or fertility preservation.
  iii. Use of hormonal contraception.
- Trial entry and randomisation more than 12 weeks after completion of breast cancer surgery.
- Planned further surgery for breast cancer, including axillary surgery, to take place after trial entry, <u>except</u> either re-excision or completion mastectomy for close/ involved margins which may be undertaken following completion of chemotherapy. *Timing of axillary radiotherapy is unrestricted.*

Please check the <u>full eligibility criteria</u> in <u>protocol v10.0</u> to ensure potential participants meet these before consenting into the study.